

**Notice of Allowability**

Application No.

09/856,937

Examiner

Diana B. Johannsen

Applicant(s)

SPOTILA, LORETTA D.

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the Interview concluding 03 March 2004.
2. ☒ The allowed claim(s) is/are 5 and 6.
3. ☐ The drawings filed on \_\_\_\_\_ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413),  
Paper No./Mail Date 0304.
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_.

### **EXAMINER'S AMENDMENT**

1. This action is in response to the telephonic interview concluding March 3, 2004. It is noted that claim 1 is canceled by the below examiner's amendment; accordingly, the remaining rejections of that claim set forth in the Final Action of September 9, 2003 are now moot. New claims 5-6 have been added by examiner's amendment and are now allowed.
  2. An extension of time under 37 CFR 1.136(a) is required in order to make an examiner's amendment that places this application in condition for allowance. During a telephone conversation conducted on March 3, 2004, Kathleen A. Tyrrell requested an extension of time for THREE MONTH(S) and authorized the Director to charge Deposit Account No. 50-1619 the required fee of \$475.00 for this extension and authorized the following examiner's amendment. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.
  3. In accordance with 37 C.F.R. 1.126, allowed claims 5-6 will be renumbered as claims 1-2, respectively (see MPEP 608.01(j)). It is noted that original claim numbers are employed in the below examiner's amendment.
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**4. The application has been amended as follows:**

**a) Cancel claim 1.**

**b) Add the following new claims:**

5) A method for identifying a human individual at risk of developing osteoporosis comprising assessing the genotype of the tumor necrosis factor alpha 2 receptor (TNFR2) gene in a sample of DNA from the individual, and identifying the individual as being at risk of developing osteoporosis if the individual possesses 3' UTR allele 1 of the TNFR2 gene.

6) The method of claim 5 wherein said 3' UTR allele 1 is indicative of low bone density levels and wherein said low bone density levels are indicative of the individual being at risk of developing osteoporosis.

**c) Amend the paragraph at page 1, following the title, as follows:**

This application is the national stage of international application PCT/US99/28403, filed November 30, 1999, [and] which claims the benefit under 35 U.S.C. 119(e) of U.S. provisional application 60/110,268, filed November 30, 1998.

**d) Change the title of the application to:**

Methods for identifying individuals at risk of developing osteoporosis.

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***Substance of interview concluding March 3, 2004***

5. On February 19, 2004, Applicant's representative contacted the examiner and requested a continuation of the discussion of allowable claim language begun in the telephonic interview that concluded on January 5, 2004. Applicant's representative provided the examiner with proposed claim language for discussion the following week. On February 25, 2004, the examiner counter-proposed allowable claim language, noting that the proposed claims were limited to the particular allele (allele 1) disclosed in the specification as being associated with osteoporosis risk, and that the proposed language would overcome remaining issues of indefiniteness. On March 3, 2004 Applicant's representative contacted the examiner and agreed to the proposed amendments. Applicant's representative also authorized the extension of time needed for entry of an examiner's amendment. New claims 5-6 are allowed.

***Conclusion***

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 571/272-0744. The examiner can normally be reached on Monday-Friday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached at 571/272-0745. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "Diana B. Johannsen", followed by a long horizontal flourish.

Diana B. Johannsen  
Patent Examiner  
March 4, 2004